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Re: Center for Biological Diversity Consent Decree and 2014 RCRA Petition

Dear Director Hoskinson:

The Vinyl Institute, Inc. (VI)[1] appreciates the opportunity to provide the U.S. Environmental Protection Agency (EPA or the Agency) with information to assist the Agency's evaluation of a July 24, 2014, Petition filed by the Center for Biological Diversity (CBD or Center). Although the VI did not object to the EPA Consent Decree with CBD,[2] this letter explains why CBD's 2014 Petition (Petition) to regulate discarded polyvinyl chloride (PVC or vinyl) as hazardous waste under the Resource Conservation and Recovery Act (RCRA)[3] *should be denied.*

PVC pipe is widely used to deliver safe drinking water consistent with federal and state regulations verified under an independent, third-party certification program administered by NSF International.[4] Consistent with regulations and building codes, durable vinyl flooring, wall covering, carpet backing, windows, doors, decks, and fences are safe to live with and play on. The Food and Drug Administration deems PVC medical devices, such as blood bags, to be safe.

Nevertheless, CBD claims that these products and many more suddenly become hazardous at the end of their useful lives and are not fit to recycle or be managed as ordinary solid waste. The Center continues to pursue its 2014 Petition even though it knows that the constituents of concern have been regulated under TSCA and RCRA for decades. Indeed, the vast majority of PVC products do not contain the constituents of concern. These comments and the enclosed

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[1] The Vinyl Institute, founded in 1982, is a U.S. trade association representing the leading manufacturers of vinyl, vinyl chloride monomer, vinyl additives and modifiers, and vinyl packaging materials. For more information, please visit: http://vinylinfo.org/.

[2] VI Comments, Document ID EPA-HQ-OGC-2022-0406-0004; *See also Proposed Consent Decree, Unreasonable Delay Claim Regarding Discarded Polyvinyl Chloride Listing,* 87 Fed. Reg. 26,351 (May 4, 2022); CBD Proposed Consent Decree, Document ID EPA-HQ-OGC-2022-0406-0002.

[3] 42 U.S.C. § 6901 *et. seq.*

[4] NSF Website, *Plastic Piping System Components*, https://www.nsf.org/testing/building-construction/plumbing-products/plastic-piping-system-components (last visited Nov. 21, 2022).

Attachment I elaborate on the errors and fallacies embodied in the petition and demonstrate why EPA must promptly deny the petition.

I. Introduction and Summary

CBD's 2014 Petition asks that EPA list PVC as a toxic hazardous waste pursuant to 40 C.F.R. § 261.11(a)(3). Petitioners allege that discarded PVC products meet the statutory and regulatory criteria for listing as a hazardous waste because they contain toxic constituents, specifically "vinyl chloride, phthalate plasticizers and other chemical additives," that present hazards cognizable under RCRA.[5]

Contrary to CBD's presumptions, existing RCRA regulation of vinyl chloride addresses potential hazards that might arise from residual vinyl chloride monomer in PVC products. Similarly, phthalates and other additives that might be present in PVC products are separately regulated by RCRA. Essentially, the Petition asks EPA to reject or ignore the regulatory program it has consistently applied since the RCRA hazardous waste identification and constituent management regulations were adopted in 1980.[6]

Under this longstanding system, discarded products are deemed hazardous waste under the toxicity characteristic only if: (1) they contain a hazardous waste constituent *and*, (2) using EPA's Toxicity Characteristic Leaching Procedure (TCLP) testing, are shown to exceed the associated regulatory limit. Accordingly, discarded PVC products already are adequately regulated under RCRA where the alleged hazardous quality arises from additives, impurities, or other constituents. Nevertheless, CBD asks EPA to reject this distinction and list discarded PVC products as hazardous waste even if the products are not hazardous when tested and when the majority of products do not contain the hazardous constituents mentioned in the Petition. In short, CBD has failed to demonstrate that its petition should be granted.

In addition, much has changed since the Petition was initially filed in 2014. This includes extensive 2016 amendments to the Toxic Substances Control Act (TSCA), enactment of the Save Our Seas 2.0 Act in 2020, and revision of the PVC MACT standard.[7] These changes demonstrate

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[5] CBD, *Petition for Rulemaking Pursuant to Section 7004(a) of the Resource Conservation and Recovery Act, 42 U.S.C. § 6974(a), and Section 21 of the Toxic Substances Control Act, 15 U.S.C. § 2620, Concerning the Regulation of Discarded Polyvinyl Chloride and Associated Chemical* Additives (Jul. 24, 2014) Document ID EPA-HQ-OPPT-2014-0684-0002, pp. 6-8 [hereinafter 2014 CBD Petition].

[6] *See*, 45 Fed. Reg. at 33,132-33,133 May 19, 1980 (Appendix VIII Hazardous Constituents list including phthalates, barium and barium compounds, cadmium and cadmium compounds, lead and lead compound, and vinyl chloride).

[7] *See* Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub.L.114-182 2018 (2016) (significantly amended TSCA and required EPA to review all existing chemicals); Save Our Seas 2.0 Act, Pub. L. 116-224 (Dec. 2020); *National Emission Standards for Hazardous Air Pollutants: Polyvinyl Chloride and Copolymers Production Reconsideration* 85 Fed. Reg. 71,490 (Nov. 9, 2020) (the PVC MACT is under reconsideration by the Agency. The PVC MACT refers to Polyvinyl Chloride and Copolymers Production: National Emission Standards for Hazardous Air Pollutants (NESHAP) - 40 CFR 63 Subparts J & HHHHHHHH and 40 CFR 63, Subpart DDDDDD, which includes lower limits on residual vinyl chloride monomer).

that listing PVC as a hazardous waste is improper even if the erroneous allegations in the Petition are assumed to be correct. Sections III through V of our comments address broad listing issues, essentially conflation and misdirection, raised by the Petition, including phthalates, marine waste, and microplastics. In Section VI, we discuss the broader policy considerations that would be undermined by the Petition.

II. Discarded PVC Products do not Meet RCRA's Hazardous Waste Listing Criteria

CBD's Petition asks that EPA list PVC as a toxic hazardous waste based on the presence of certain hazardous constituents in the waste under 40 C.F.R. § 261.11(a)(3). To list a waste as a toxic hazardous waste under this provision, EPA must conclude that the waste is capable of posing a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed, considering 11 factors.[8]

According to the Petition, several substances that may be components in some PVC products are hazardous constituents under RCRA Appendix VIII: vinyl chloride, butyl benzyl phthalate (BBP, CASRN 85-68-7), dibutyl phthalate (DBP, CASRN 84-74-2), diethyl phthalate (DEP, CASRN 84-66-2), diethylhexyl phthalate (DEHP, CASRN 117-81-7), dimethyl phthalate (DMP, CASRN 131-11-3), di-n-octyl phthalate (DNOP, CASRN 117-84-0), lead (CASRN 7439-92-1), cadmium (CASRN 7440-43-9), and barium (CASRN 7440-39-3).[9] Given their regulatory status and the RCRA regulatory scheme, these do not provide a basis for a RCRA listing of PVC products, particularly given their absence or limited presence as constituents.

Other phthalate plasticizers have been included in EPA's Phthalates Action Plan.[10] These substances are not listed as hazardous constituents under RCRA, but their use in PVC products is marginal. The ongoing and planned review of phthalates under TSCA further weights against the need for the agency to review these substances under RCRA now or consideration of PVC products as hazardous waste under Part 261.[11]

A significant deficiency in CBD's Petition is that CBD refers to PVC as if it were a single product, substance, or mixture. This approach discounts the wide range of vinyl polymers and copolymers produced by the industry. There are more than one hundred unique PVC resins produced in the U.S. that are used in literally thousands of grades for a myriad of vinyl applications. As a general matter, resin recipes vary widely, and are often specific to a particular customer's specifications (based on the ultimate product) as well as the particular machinery and processes used by a manufacturer to produce PVC products. For example, vinyl pipe uses

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[8] 40 C.F.R. § 261.11(a)(3).

[9] Appendix VIII to 40 C.F.R. Part 261.

[10] *See* EPA, Phthalates Action Plan (Mar. 2012), [HYPERLINK "https://www.epa.gov/sites/default/files/2015-09/documents/phthalates_actionplan_revised_2012-03-14.pdf"] (listing diisobutyl phthalate, di-n-pentyl phthalate, diisononyl phthalate, and diisodecyl phthalate).

[11] *See* 40 C.F.R. § 261.11(a)(3).

significantly different additives and manufacturing processes than flexible medical tubing. These recipes will have varying concentrations of additives and may not have all (or any) of the hazardous constituents noted above.

Consequently, CBD's monolithic view of "PVC" is entirely inappropriate, and EPA must consider the required 11 factors as they apply to particular PVC compounds, rather than with regard to all PVC compounds. This is unlike the situation in *Dithiocarbamate Task Force v. EPA*,[12] as it is not reasonable to infer the presence of phthalates or stabilizers in PVC throughout the class. For these reasons, it is far more sensible for EPA to adhere to the current regulatory structure under which discarded PVC products are deemed hazardous waste only if they contain a hazardous waste constituent and, upon TCLP testing, exceed the associated regulatory limit.

Section 260.20 of the RCRA regulations governs rulemaking petitions but does not prescribe specific, substantive requirements for hazardous waste listing petitions (in contrast to petitions to add a testing or analytical method, for example). That said, caselaw has established that EPA must address all 11 factors as it considers whether to list a waste under section 261.11(a)(3).[13] Accordingly, a petition should be denied if the Agency's preliminary review does not find reasonable support for each of the 11 factors.

In this section we discuss some of the more egregious flaws in the information included in CBD's Petition. We also include as **Attachment I** a document entitled *Vinyl Institute Comments on Center for Biological Diversity Petition References* which lists the studies, reviews, and other information cited in the CBD Petition and demonstrate that they are irrelevant or unsupportive of the Petition's central claims regarding the potential hazard of discarded PVC products. In short, the Petition has failed to directly address or demonstrate that those criteria are satisfied and that discarded PVC products pose a substantial hazard to human health or the environment.

A. Nature of the Toxicity Presented by the Constituent

CBD presents a variety of studies to support its allegations of hazard presented by PVC waste. Lines 30 through 84 of **Attachment I** set out the reasons why we disagree. Current agency regulation provides a sound mechanism for determining whether waste should be deemed hazardous under RCRA. We are not aware of any new studies that would change the Agency's safety assessment of vinyl chloride or other constituents.[14]

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[12] 98 F.3d 1394, 1399 (D.C. Cir. 1996).

[13] *Dithiocarbamate Task Force v. EPA*, 98 F.3d 1394, 1402 (D.C. Cir. 1996) (stating that "[t]he theory that § 261.11(a)(3) does not require consideration of the ten factors defies the language of the rule . . . Its structure is simple. Given an Appendix VIII listing, the Administrator makes a determination about "hazard to human health or the environment," "after considering" the named factors.").

[14] *See* EPA, *Toxicological Review of Vinyl Chloride in Support of Summary Information on the Integrated Risk Information System (IRIS)* at 40 (May 2000), https://iris.epa.gov/static/pdfs/1001tr.pdf. IRIS reviews for phthalates and other constituents can be found on the IRIS webpages.

If EPA was to entertain the petition, the Agency must prepare a robust risk assessment that begins with a systematic review of the scientific and technical literature and include input from peer reviewers and the regulated community, rather than the piecemeal studies cited by CBD.[15] As discussed below in Section IV, such reviews are part of the existing chemical review process after the 2016 amendments to TSCA.[16]

B. Concentration of the Constituent in the Waste

Contrary to CBD's allegations, PVC resin does not include "significant" concentrations of vinyl chloride.[17] The production of PVC has been regulated under the Clean Air Act via the *National Emission Standard for Vinyl Chloride* (VCM NESHAP) since 1976[18] and via the *National Emissions Standard for Hazardous Air Pollutants for Polyvinyl Chloride and Copolymers Production* ("PVC MACT")[19] since 2015. As the rulemaking for the PVC MACT demonstrated, residual vinyl chloride monomer (RVCM) concentrations in resin decreased between 1976 and 2012, and the MACT approach is designed to drive further decreases.

VI's 2014 comments referenced a survey for the year 2000 indicating residual vinyl chloride levels of below 1 ppm on a weighted industry average basis for all PVC resins.[20] With regard to PVC pipe resin, which constitutes approximately 45 percent of the vinyl market, a 2001 report by NSF International found that there was no detectable VCM in 86 percent of the PVC pipe sampled and in 88 percent of the PVC fitting sampled.[21] According to EPA's Second Six Year Review of Drinking Water Contaminants, the minimum detection limit for test method 502.2 for vinyl chloride is 0.18 ug/l.[22]

The 2000 survey was updated in 2017.[23] The 2017 update was informed by a VI survey of PVC producers and NSF International PVC Pipe and Fittings Testing (January 1, 1998, through

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[15] National Academies of Sciences, Engineering, and Medicine, *The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations* at 3 Figure S-1 (Washington, DC: The National Academies Press, 2021), https://doi.org/10.17226/25952.

[16] *See*, Section 3.A, above.

[17] Lines 85 through 97 of **Attachment I** present our views on the references CBD relies on for this listing criteria.

[18] 40 C.F.R. Part 61, Subpart F.

[19] *See e.g.*, 40 C.F.R. Part 63, Subpart DDDDDD and Subpart HHHHHHHH.

[20] Borrelli, de la Cruz, Paradis, *Residual Vinyl Chloride Levels in US PVC Resins and Products: Historical Perspective and Update*, Journal of Vinyl Additive Technology, 65-66 (April 2005).

[21] C.J. McLellan, *Test results of residual vinyl chloride monomer (RVCM) measurements from polyvinyl (PVC) pipes and fittings: 2001*, NSF International.

[22] U.S. EPA, *Development of Estimated Quantitation Levels for the Second Six Year Review of National Primary Drinking Water Regulations* p. 4-31 (Oct. 2009), https://www.epa.gov/sites/default/files/2014-12/documents/815b09005_0.pdf. Vinyl Chloride was among the regulated contaminants deemed to be ineligible for revision during the third six year review that occurred in 2017.

[23] Paradis, Borrelli, Krock, de la Cruz and Purkiss, *Residual Vinyl Chloride Levels in US PVC Resins -Update* 2017 (paper presented at Vinyltec 2017, Society of Plastics Engineers, Anaheim, California).

October 18, 2000). The following table presents the results of both the 2000 and 2017 surveys, reflecting a continuing decline in RVCM levels.

Table 2: Vinyl Institute RVCM Survey Results [1] Comparison

Resin Type, IV	Use	Weighted-average RVCM, YTD 2000 (ppm, weight)	Average Typical RVCM 2017, ppm
Suspension 0.65 – 0.82	Rigid Molding, Sheet, Film	0.66	0.23
Suspension 0.82-0.92	Rigid Pipe, Rigid Profile	1.03	0.24
Suspension 0.92-1.0	GP Flex	0.52	0.15
Suspension 1.0+	High Strength Flex		0.17
Dispersion / Emulsion	Gen. Purpose	1.45	0.90

1] Results reflect all VI member company PVC manufacturers, which in 2017 included all US producers

More than 96.6 percent of pipe tested by NSF International were non-detectable for RVCM at 0.1 ppm. The overall average of RVCM in PVC resin continues to decline compared to 2000. Reduction of monomer to these levels ensures the PVC products are safe for use when recycled or discarded.

With regard to plasticizers, CBD's Petition assumes that all plasticizers used in PVC resins are phthalate esters. In fact, a number of other compounds are used. The FDA, for example, has cleared a number of non-phthalate plasticizers that may be used in flexible vinyl formulations.[24] These include a number of citrate plasticizers, such as triethyl citrate. As noted above, only flexible PVC applications, which account for 25% of PVC production, use plasticizers, and nonphthalate plasticizers are increasingly expected to replace phthalates.[25]

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[24] 21 C.F.R. § 181.27.

[25] IHS Markit, Plasticizers – Chemical Economics Handbook (May 2021), [HYPERLINK "https://ihsmarkit.com/products/plasticizers-chemical-economics-handbook.html"] (stating that "phthalates accounted for over 55% of world consumption of plasticizers in 2020, down from approximately 60–65% . . . the decrease in market share has largely been due to . . . rapid consumption growth for nonphthalate plasticizers, mainly terephthalates, epoxy, aliphatics, and benzoates, as replacements for DEHP and other phthalates" and other factors).

C. Potential for Constituents to Migrate under Improper Management

Contrary to CBD's Petition, PVC is not "intrinsically unstable."[26] Rather, most finished PVC products, such as PVC pipe, are inert.[27] Due to its non-corrosive nature, the estimated life for PVC pipe has been increased to 110 years by the American Water Works Association Research Foundation (AWWARF).[28] In addition, data indicate that manufacturing for PVC products, which subjects PVC to more stressful forces than end-of-life disposal, do not result in any release or migration of constituents in PVC. Typical processing conditions take place at a melt temperature of greater than 350°F and under greater than 2,000 psi machine pressure. Studies of workplace exposure found that vinyl chloride was undetectable near equipment processing rigid and flexible vinyl polymers,[29] making clear that PVC does not release or degrade into vinyl chloride monomer even under the most intense conditions. Moreover, the low level of vinyl chloride in today's PVC products ensures that little migration can occur.

Indeed, PVC is widely used in landfill caps, landfill covers, landfill liners, temporary landfill closures and other landfill related applications, due to its ability to accommodate differential settlement in the waste pile. Its high elongation and durability make PVC an excellent environmental liner for these applications. First utilized as bottom liners for municipal waste containment and landfill closures to inhibit rainwater leakage, PVC has over four decades of success in the landfill closure market, effectively helping to preserve groundwater resources. PVC geomembrane is a material of choice for:

- Municipal solid waste (MSW), and yard waste (in several states) landfill disposal facilities
- Low-hazard industrial waste, C&D construction, and demolition waste debris, other non-hazardous industrial waste landfill disposal facilities
- Coal ash basin closure, and
- Facilities that accept fly ash, cement kiln ash, wood ash, lime kiln dust, and foundry sands[30]

A similar conclusion can be drawn for flexible PVC products. In his report to the Australian Government on environmental impacts of PVC materials at their end of life, Dr. John Scheirs summarized the work of Ivo Mersiowsky and his colleagues in this manner:

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[26] Lines 98 through 114 of **Attachment I** present our views on the references CBD relies on for this listing criteria.

[27] Wilkes, Charles, Summers, James W., and Daniels, Charles A. (eds.), PVC Handbook (2005) at 657 657 [hereinafter "PVC Handbook"].

[28] Burn, S. et. al., *Long-term Performance Prediction for PVC Pipes*, AWWARF Report 91092F, May 2006.

[29] PVC Handbook at 652-53.

[30] *See* e.g., Florida Administrative Code § 2-701.600(3)(g)4; *see also*, USDA, Natural Resources Conservation Service, *Conservation Practice Standard Pond Sealing or Lining, Geomembrane or Geosynthetic Clay Liner*, 21-CPS-1.

> *The long-term behaviour of plasticised PVC products (cable material and a flooring with different combinations of plasticisers) was investigated by Mersiowsky (2001b) in landfill simulation reactors. The behaviour of the various plasticisers was found to differ significantly. Losses of DEHP and BBP from the flooring were too low for analytical quantification. No loss of DIDP from the cable was detectable whereas DINA in the same product showed considerable losses of up to 70% compared to the original contents. The loss of DINA was attributed to biodegradation rather than leaching (Mersiowsky, 2001b).*[31]

More recent evidence can be found in Exxon Mobil's submission for REACH Authorization. The submission identified key qualities of plasticizer volatility and water solubility, highlighting the differences between certain grades of phthalate plasticizers used in PVC and explaining that polar bonds between PVC resin and plasticizers used in flexible applications aid in their long-term retention:

> *The factors that will affect the choice of plasticizers for specific uses include plasticizer vapor pressure, boiling point but also viscosity and diffusion coefficient. These physico-chemical properties alter with increasing molecular weight and level of branching.*[32]
>
> *The bond between PVC and plasticizer exists and can be measured. Analysis of flexible PVC by FTIR (Fourier transform Infrared) spectrography shows that when plasticizers exhibit their plasticizing properties, there is a spectral shift of the plasticizer carbonyl bond in the ester and the carbon-chlorine bond in PVC (frequency of the carbonyl bond is reduced). The lower frequency is a result of the physical interaction. The bond is at the heart of the physical properties of flexible PVC. ...In absence of durable bonds or interactions, flexible PVC would not be used to produce durable goods like cables, roofing, geo-membranes, etc.*[33]

The CBD petition assumes that PVC products will be improperly managed but provides no evidence that this is so. Lines 115 through 181 of **Attachment I** present our view on the references relied on by CBD to address the requirements of 40 C.F.R. §§ 261.11(a)(3)(iv)-(viii). Notably, none of the studies, and this is the case for the preponderance of references cited by CBD, address waste or materials found or produced in the U.S. Differences in regional production standards and waste management practices must be considered. In this case, we submit that these studies are not representative of U.S. conditions and provide insufficient evidence to support listing. Similarly, the studies fail to demonstrate that PVC forms a large

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[31] Scheirs, Dr. John, *ExcelPlas Polymer Technology, End-of-Life Environmental Issues with PVC in Australia*, June 17, 2003; Ivo Mersiowsky, *Fate of PVC Polymer, Plasticizers, and Stabilizers in Landfilled Waste*, Journal of Vinyl and Additive Technology, Vol 8, No. 1 (March 2002).

[32] Submission of information on DINP CAS#68515-48-0, EC#271-090-9 as an alternative to DEHP Applications for Authorisation, ExxonMobil Petroleum and Chemical B.V.B.A., Jan. 7, 2014.

[33] *Id.* at 6. *See also infra* note 50.

component of microplastics found in marine environments. Indeed, a preponderance of the studies cited by CBD that evaluated microplastics identified polymers other than PVC.

In addition, EPA prepares and updates a sustainable materials management report, formerly called Municipal Solid Waste in the United States: Facts and Figures. It includes information on municipal solid waste (MSW) generation, recycling, combustion with energy recovery and landfilling. The fact sheet also includes information on Construction and Demolition Debris generation, which is outside of the scope of MSW.[34] EPA's report does not support the Petition's allegation of improper management and reveals improved solid waste management in the United States.[35]

> *Over the last few decades, the generation, recycling, composting, combustion with energy recovery and landfilling of MSW has changed substantially. Solid waste generation peaked at 4.74 pounds per person per day in 2000 and 2005, falling to 4.51 pounds per person per day in 2017. The higher rate of 4.91 pounds per person per day in 2018 reflects the change in food waste measurement methodology.*[36]
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> *The combined recycling and composting rate increased from less than 10 percent of generated MSW in 1980 to 35.0 percent in 2017. In 2018, the recycling and composting rate was 32.1 percent (See Figure 2). Without including composting, recycling alone rose from 14.5 million tons (9.6 percent of MSW) in 1980 to 69 million tons (23.6 percent) in 2018. Although more tons were recycled in 2018 than ever before, the recycling rate decreased to the lowest levels since 2006. Composting was negligible in 1980, but it rose to 24.9 million tons in 2018 (8.5 percent).*

D. Nature and Severity of Past Human Health and Environmental Damage

CBD's petition engages in unsupported speculation that fails to establish any causal connection between PVC waste, exposure to phthalates, and harm to health or the environment. In addition, CBD's petition fails to distinguish between exposure due to improper disposal and exposure due to use of substances that contain phthalates, which is not relevant to the listing of hazardous waste under section 261.11(a)(3).[37]

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[34] EPA Website, *Advancing Sustainable Materials Management: Facts and Figures Report*, [HYPERLINK "https://www.epa.gov/facts-and-figures-about-materials-waste-and-recycling/advancing-sustainable-materials-management"] (last visited Nov. 21, 2022).

[35] EPA, *Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Materials Generation and Management in the United States* p. 8 (Dec. 2020), [HYPERLINK "https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf"].

[36] In 2018, for the first time in this report series, EPA revised its food measurement methodology to more fully capture flows of excess food and food waste throughout the food system. The resulting category, other food management pathways, accounted for 17.7 million tons (6.1 percent) (*See id.* at Figure 3, Table 2 and text box for details).

[37] *Dithiocarbamate Task Force v. EPA*, 98 F.3d 1398, 1401 (D.C. Cir. 1996) ("Hazards from the proper use of such chemicals might justify a ban under FIFRA, 7 U.S.C. § 136a(c)(5)(D) (requiring, as predicate to registration of a

EPA should give greater weight to evidence that humans and mammals metabolize phthalates differently than rodents. A recent study, conducted by Brown University researchers sponsored by the National Institute of Health, indicated that dibutyl phthalate, one of the more studied phthalates as far as rodent effect data, did not affect male infant reproductive stem cells implanted into rodents in a manner as previously believed:[38]

> Importantly, *ex vivo* fetal testis phthalate exposure does not recapitulate the species-specific [rodent] endocrine disruption, demonstrating the need for a new bioassay to assess the human response to phthalates. ....
> **Results:** Consistent with the *in utero* response, phthalate exposure induced MNG formation in rat and mouse xenografts, but only rats exhibited suppressed steroidogenesis. Across a range of doses, human fetal testis xenografts exhibited MNG induction but were resistant to suppression of steroidogenic gene expression.
> **Conclusions:** Phthalate exposure of grafted human fetal testis alters fetal germ cells, but does not reduce expression of genes regulating fetal testosterone biosynthesis.[39]

Lines 182 through 194 of **Attachment I** present additional information on the relevance of the studies relied on by CBD for this listing criteria.

E. Action Taken by Other Government Agencies or Regulatory Programs

EPA's hazardous waste listing determination policy states:

> *[I]f other Federal or State programs clearly regulate risk associated with the waste stream, listing may not be necessary to eliminate risk. . . . In some cases, another regulatory program may be in the process of developing such regulatory requirements. If this program is under statutory requirements or Court Order, EPA may consider these regulatory requirements to be forthcoming and, in some cases, may defer to them in listing determination, even where such regulatory coverage is several years away. If this*

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pesticide, determination that 'when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects [sic] on the environment'), but that is not the purpose of RCRA. Outside the area of increases in mortality or serious illnesses, see 42 U.S.C. § 6903(5)(A), which EPA does not appear to invoke here, the statute is concerned with the hazards of a substance when 'improperly treated, stored, transported, or disposed of, or otherwise managed.' *Id.* at § 6903(5)(B)") (error in original). *See also*, 59 Fed. Reg. at 66,078 ("For each listing determination, EPA seeks data on damage cases. These are cases in which some prior waste management practice" – as opposed to exposure based on a use pattern – "has resulted in environmental harm").

[38] Heger, N. E., et.al, *Human Fetal Testis Xenografts Are Resistant to Phthalate-Induced Endocrine Disruption*, National Institute of Environmental Health Sciences - NIH, Environmental Health Perspectives, April 17, 2012.

[39] *Id.* at 4.

> *program is under no statutory or legal deadline, no deference typically will be given to projected future regulatory coverage from other programs.*[40]

Several of the constituents mentioned in CBD's petition are already RCRA hazardous waste constituents under the toxicity characteristic: vinyl chloride, lead and lead compounds, cadmium and cadmium compounds, and barium and barium compounds.[41] Any solid waste (including discarded PVC materials) is regulated as hazardous waste if one of these substances is present in the solid waste above the regulatory level for that substance.[42] For these substances, EPA has established a regulatory level under RCRA, and it is entirely unnecessary for EPA to further regulate these substances by listing PVC products. Additionally, and as discussed above, residual vinyl chloride is currently regulated in PVC resin under the Clean Air Act.[43]

As noted at line 203 of **Attachment I**, CBD mischaracterizes the data on landfill bans of PVC in other countries. According to the Nordic Council of Ministers:

> *Landfill bans of organic and combustible waste (in Finland and Sweden) and high costs for landfilling were among the main reasons for less PVC going to landfilling and most being incinerated with energy recovery. Denmark is the only country where landfilling of soft PVC is legal, but even here landfilling is minor. The largest share of PVC enters incineration through mixed waste streams.*[44]

Other countries, such as Australia, have studied end-of-life PVC materials disposition and have concluded that the risk is so low that they would not take any action to regulate its disposal.[45] A comprehensive study for Europe's Vinyl 2010 project was prepared by PE Europe GMBH and included a section that studied alternative dispositions to PVC wire and cable at its end of life in a landfill scenario.[46] While this study focuses on energy recovery, it provides a good analysis of the low risk of PVC materials disposed in a landfills.

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[40] *Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Dye and Pigment Industries; Hazardous Waste Listing Determination Policy; and CERCLA Hazardous Substance Designation and Reportable Quantities,* 59 Fed. Reg. 66,072, 66,078 (Dec. 22, 1994).

[41] 40 C.F.R. § 261.24, Table 1.

[42] *Id.* at § 261.24(a).

[43] *Supra*, notes 18 and 19.

[44] *See* Nordic Council of Ministers, *PVC Waste Treatment in the Nordic Countries* (2019), [HYPERLINK "https://norden.diva-portal.org/smash/get/diva2:1287469/FULLTEXT01.pdf"].

[45] Scheirs, Dr. John, *ExcelPlas Polymer Technology, End-of-Life Environmental Issues with PVC in Australia*, June 17, 2003.

[46] J. Kreissig et al., *PVC Recovery Operations, Environmental and Economic Systems Analysis*, PE Europe GmbH, April 2003.

III. Phthalates are not an Inherent Component of PVC, are Separately Regulated under RCRA, and Being Addressed Under TSCA

As the VI reported in its 2014 comments,[47] phthalates are not relevant to listing PVC because most vinyl materials do not contain phthalates. Roughly 75 percent of all vinyl material produced in the U.S. is rigid and does not contain phthalate plasticizers.[48] In addition, not all PVC products that are plasticized contain phthalate plasticizers. Non-phthalate varieties also are used to impart performance requirements for the intended product application.[49]

A. Vinyl resin, plasticizers, phthalates, compounds, and PVC products

PVC is a widely used polymer. It is composed of two simple building blocks: chlorine, based on common sea salt, and ethylene, derived from natural gas liquids. PVC resin can be used to produce rigid products but also can be made flexible.

Rigid PVC is used for large and small diameter pipes, residential siding, window frames, and heavy industrial applications. Seventy-five percent of PVC resin is employed in products that are rigid, *i.e.*, non-flexible. Examples of flexible PVC applications include electrical cables, fabrics and upholstery, hazard suits for hospital workers, blood bags, roofing, flooring and wall coverings for homes, hospitals, and businesses, food packaging, and pharmaceutical safety seals.

Plasticizers, of which phthalates are but one group of specific chemicals, are used to make rigid polymers flexible. As the Petition notes, phthalates are not chemically bound to the PVC polymer chain. A simple analogy describes plasticizers as a thick oil mechanically compounded into the polymer chains. For PVC, the analogy is misleading because phthalates are held in the polymer structure. The bond strength is measurable. Various attractive forces hold the phthalate within the PVC matrix, limiting migration. Thus, retention in the polymer matrix is one of the main factors in considering which plasticizer to use. Due to their low vapor pressure, phthalates

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[47] Letter from the Vinyl Institute, Inc. to the Director of the Office of Pollution Prevention and Toxics and the Director of the Office of Resource Conservation and Recovery (Oct. 15, 2014), Docket I.D. EPA-HQ-OPPT-2014-0684-0006.

[48] *See* Borrelli, de la Cruz, Paradis, *Residual Vinyl Chloride Levels in US PVC Resins and Products: Historical Perspective and Update*, Journal of Vinyl Additive Technology, 65-66 (April 2005). The VI estimates that the ratio of rigid and flexible PVC has not changed significantly since publication of Borrelli's article. Pipe, siding, windows, doors, fence, and deck applications, totaling 65%, are rigid PVC products that are not plasticized. The remaining applications include both rigid and flexible-plasticized products, which include calendared packaging, extruded film & sheet, cable, and flooring).

[49] For example, the Food and Drug Administration (FDA) has cleared the use of various non-phthalate plasticizers in flexible vinyl formulations used for packaging and other food-contact applications and medical devices. 21 C.F.R. § 178.3740 (listings for 1,3-Butylene glycoladipic acid polyester; Di(C7, C9-alkyl) adipate; Di-n-alkyl adipate; Diisononyl adipate; Propylene glycol azelate).

are often the plasticizer of choice for long service applications because they maintain product flexibility and a service life for years and decades.[50]

The term "phthalate" refers to a family of chemicals that are structurally similar, but which are functionally and toxicologically distinct from one another. Phthalates are categorized as high or low depending on their molecular weight. High molecular weight phthalates (high phthalates), such as di-isodecyl phthalate (DIDP) and di-isononyl phthalate (DINP), have seven or more carbon atoms in their chemical backbone that gives them increased permanency and durability. High phthalates have been studied and reviewed by government scientific agencies and regulatory bodies worldwide. These agencies have found that high phthalates are safe for existing use.[51]

B. RCRA Regulation of Phthalates

The distinction between phthalates and PVC has been recognized under the RCRA regulations since 1980.[52] EPA has consistently regulated phthalates separately from PVC. This is proper because phthalates, like other plasticizers, are neither inherent nor essential to many PVC applications. This is not to suggest that phthalates are unimportant or unessential for certain performance properties, but only to demonstrate that the Petitioners' attempt to list PVC as hazardous based on an additive used in a minority of applications is unfounded and would create a troublesome precedent for many other materials that combine various components to achieve necessary performance functions.

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[50] Phthalate Esters in The Handbook of Environmental Chemistry" C.A. Staples, Volume Editor, Vol. 3 Anthropogenic Compounds Part Q (2003. The Handbook explains that "Phthalate esters are not bound to the polymer with covalent bonds and are therefore able to migrate to the surface of the polymer matrix where they may be lost by a variety of physical processes. Nevertheless, various chemical-physical attractive forces hold the phthalate tightly within the vinyl matrix, so that such migration occurs at a very low rate." Therefore, "retention in the polymer matrix is one of the main factors in considering which phthalate ester to use. The ester must be sufficiently nonvolatile to remain in the compound during its mixing and formulation stages." *See also supra* note 33 at 6.

[51] *See* American Chemistry Council, *High Phthalates,* [HYPERLINK "https://www.americanchemistry.com/industry-groups/high-phthalates"] (last visited Oct. 13, 2022). For a list of studies, *see* American Chemistry Council, *Industry Group Resources*, [HYPERLINK "https://www.americanchemistry.com/industry-groups/resources?filters%5Bindustry_groups%5D%5B%5D=high+phthalates&filters%5Bresource_type%5D%5B%5D=research&sort%5Bdate%5D=desc&page=3"] (last visited Nov. 21, 2022).

[52] See, 45 Fed. Reg. at 33,132-33,133 (May 19, 1980) (Appendix VIII Hazardous Constituents list including phthalates, barium and barium compounds, cadmium and cadmium compounds, lead and lead compound, and vinyl chloride); 86 Fed. Reg. 28,196, 28,305-29,310 (Aug. 6, 1986); 53 Fed. Reg. 13,382, at 13,389 (Apr. 22, 1988), (EPA, Hazardous Waste Management System: Identification and Listing of Hazardous Waste) (phthalates listed of hazardous constituents in Appendix VIII to 40 C.F.R. Part 261).

As the Petition notes, several substances that are components in some PVC compounds are regulated as hazardous constituents under RCRA:[53]

- butyl benzyl phthalate (CASRN 85-68-7),
- dibutyl phthalate (CASRN 84-74-2),
- diethyl phthalate (CASRN 84-66-2),
- diethylhexyl phthalate (DEHP, CASRN 117-81-7),
- dimethyl phthalate (CASRN 131-11-3), and
- di-n-octyl phthalate (CASRN 117-84-0).

Although other phthalate plasticizers were included in a 2012 EPA Phthalates Action Plan,[54] as explained in Section III, the 2016 amendments to TSCA superseded the old plan. The potential presence of these phthalates in PVC resins is not a basis for listing discarded PVC products because: (1) 75 percent of PVC products do not contain phthalates, (2) phthalates are being addressed separately by EPA under TSCA, and (3) such a listing would conflict with the Agency's consistent, precedential, and rule-base practices for managing product constituents under RCRA.[55]

C. RCRA treatment of stabilizers and residual vinyl chloride in PVC products

The Petition seeks to list PVC based on stabilizers that may be used in PVC products. Like phthalates, the stabilizers are not inherent to PVC. Heat stabilizers are antioxidants that are used to reduce the degrading effects of heat generated during processing of the biopolymer composition under severe conditions (shearing, temperature, and oxygen).[56] The heavy metal compounds that Petitioners reference have been listed as hazardous constituents for decades,

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[53] See Appendix VIII to 40 C.F.R. Part 261 and *supra* note 5.

[54] *See* EPA, *Phthalates Action Plan (Mar. 2012)*, [HYPERLINK "https://www.epa.gov/sites/default/files/2015-09/documents/phthalates_actionplan_revised_2012-03-14.pdf"] (listing diisobutyl phthalate, di-n-pentyl phthalate, diisononyl phthalate, and diisodecyl phthalate).

[55] *See* 40 C.F.R. § 261.11(a)(3). Although other phthalate plasticizers have been included in EPA's Phthalates Action Plan, as noted by CBD, these substances are not listed as hazardous constituents under RCRA. Consequently, the potential presence of these substances in PVC resins is irrelevant to consideration of whether PVC resins should be listed as hazardous waste under Part 261.

[56] Polymer stabilizers are combined with polymeric materials, such as plastics and rubbers, to inhibit or retard their degradation. Common polymer degradation processes include oxidation, UV-damage, thermal degradation, ozonolysis, as well as reactions with catalyst residues, dyes, or impurities. These degrade the polymer at a chemical level, via chain scission, uncontrolled recombination, and cross-linking, which adversely affects many key properties such as strength, malleability, appearance, and color. Zweifel, Hans; Maier, Ralph D.; Schiller, Michael (2009). Plastics additives handbook (6th ed.). Munich: Hanser. ISBN 978-3-446-40801-2; Singh, Baljit; Sharma, Nisha (March 2008). "Mechanistic implications of plastic degradation". Polymer Degradation and Stability. 93 (3): 561–584. doi:10.1016/j.polymdegradstab.2007.11.008.

including lead and lead compounds (CASRN 7439-92-1), cadmium and cadmium compounds (CASRN 7440-43-9), and barium and barium compounds (CASRN 7440-39-3).[57]

Critically, the use of heavy metal lead, cadmium, and barium stabilizers in PVC products has been essentially eliminated through the successful substitution of other stabilizers over the past several decades. Lead stabilizer was never used in PVC pipe and was completely discontinued in other rigid PVC products between the late 1960's and mid-1990's. Lead stabilizer use was discontinued in PVC in wire and cable applications by 2007.

Like phthalates and heavy metal stabilizers, vinyl chloride monomer is listed in Appendix VIII to 40 C.F.R. Part 261, and subjects PVC product constituents to prescribed test and migration limits. These existing RCRA regulations are supplemented by upstream Clean Air Act regulations, which impose limits on residual vinyl chloride in PVC resin as a means of ensuring that exposure to vinyl chloride monomer is limited and safe. These appear in the vinyl chloride NESAHP[58] and the PVC MACT.[59]

IV. EPA is Reviewing and Managing Phthalates and Other Chemicals Under the Amended Toxic Substances Control Act

Even if phthalates were relevant to listing discarded PVC products, the Agency has not only regulated phthalates under RCRA, but is also undertaking comprehensive reviews under TSCA. This is an independent basis for not listing PVC based on Petitioners' attempt to treat PVC and phthalates as a single substance under RCRA.[60]

A. TSCA Existing Chemicals Review Process

Much has changed since 2014 when CBD submitted its petition. Congress enacted TSCA to prevent the unreasonable risks associated with certain chemical substances.[61] In 2016, Congress amended TSCA through the Frank R. Lautenberg Chemical Safety for the 21st Century Act, creating "a process under which EPA will for the first time systematically review the safety of

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[57] Appendix VIII to 40 C.F.R. Part 261.

[58] *See*, 40 CFR Part 61 Subpart F (limiting suspension resins, the type of resin that would be plasticized, to a 400 ppm limitation).

[59] 40 CFR Part 63, subparts JJJJJJ and GGGGGGG. The PVC MACT superseded the NESHAP, but the PVC MACT is under reconsideration by the agency, *see* 85 Fed. Reg. 71,490 (Nov. 9, 2020).

[60] EPA denied the TSCA portion of Petitioner's 2014 petition, a decision with which we agree. That denial is not relevant to the agency's current TSCA activities and obligations arising from the 2016 amendments to TSCA discussed in these comments. 79 Fed. Reg. 64,722 (Oct. 31, 2014).

[61] *See* 15 U.S.C. §§ 2601-97. S. Rep. No. 94-698, at 5 (1976), reprinted in Legislative History of TSCA at 161; H.R. Rep. No. 94-1341, at 1, 6 (1976), reprinted in Legislative History of TSCA at 409, 414 (Comm. Print 1976). The summary of TSCA in section A is based on the Agency's opening brief in *Safer Chemicals Healthy Families* v. *U.S. EPA*, Case No. 17-72260 and consolidated cases, U.S. Court of Appeals for the 9th Circuit, August 6, 2018.

chemicals in active commerce," while enabling EPA to focus on "priority chemicals" and "conditions of use that raise the greatest potential for risk."[62]

EPA is already reviewing phthalates under TSCA. This will include a "risk evaluation" that considers the potential hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations for each chemical that EPA expects to consider.[63] EPA then must determine whether the chemical poses an unreasonable risk to human health or the environment under the conditions of use included within the scope of the risk evaluation.[64]

A chemical deemed to pose an unreasonable risk under any of its conditions of use moves to the "risk management" phase.[65] There, EPA must impose requirements on the chemical as necessary to remove the unreasonable risk. This process is aligned with the Petition's request and goals as explained in the following subsection.

B. TSCA Implementation and Phthalates

Consistent with Congressional direction now embodied in the Agency's TSCA regulations, chemicals in the 2014 update to the Agency's TSCA Work Plan for Chemical Assessments are preferred candidates for Prioritization.[66] The Agency must identify "a sufficient number of candidates from the 2014 update of the TSCA Work Plan for Chemical Assessments to ensure that, at any given time, at least 50 percent of risk evaluations being conducted by EPA are drawn from that list until all substances on the list have been designated as either a High-Priority Substance or Low-Priority Substance . . . ."[67]

The TSCA Work Plan lists 90 substances in alphabetical order, including the phthalates on which the Petition focused.[68] In December 2019, EPA designated 20 High-Priority substances to undergo risk evaluation under TSCA.[69] Risk evaluations are subject to a statutory three-year deadline for completion, which may be extended up to six months by the Agency. Thus, these risk evaluations must be completed by December 2022 or June 2023. If any condition of use is

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[62] 162 Cong. Rec. at S3516 col. 3, S3519 col. 3.

[63] 15 U.S.C. §§ 2605(b)(2)(A)-(B), 2605(b)(3)(A), 2605(b)(4)(D).

[64] *Id.* § 2605(b)(4)(A).

[65] *Id.* § 2605(a)(1).

[66] EPA, *TSCA Work Plan for Chemicals Assessments: 2014 Update (Oct. 2014)*, https://www.epa.gov/sites/default/files/2016-02/documents/tsca_work_plan_2014_update_tables.pdf [hereinafter TSCA Work Plan].

[67] 40 C.F.R. §§ 702.5(c) and (c)(2).

[68] TSCA Work Plan at pp. 5-13 (chemicals #16, 25, 34-38, 41).

[69] *High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances*, 84 Fed. Reg. 71,924-71,935 (Dec. 30, 2019).

found to present a significant risk, a rulemaking of two to three years will automatically commence.[70] EPA designated the five phthalates listed below as High-Priority substances.

The scope of a risk evaluation includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider. The scope will also include: (1) a Conceptual Model, which will describe the relationships between the chemical, under the conditions of use, and humans and the environment, and (2) an Analysis Plan, which will identify the approaches and methods EPA intends to use to assess exposures and hazards.

A chemical-specific scope document is prepared describing that substance's risk evaluation. A draft is published within three months from the initiation of the risk evaluation process with a 45-day public comment period on the draft scope. A final scope is published within six months after initiation of the risk evaluation, as required by the statute. Consistent with this process, in August 2020, EPA published final scope documents for the following five phthalate plasticizers:

- Diethylhexyl Phthalate (CASRN 117-81-7),[71]
- Dicyclohexyl Phthalate (CASRN 84-61-7),[72]
- Diisobutyl Phthalate (CASRN 84-69-5),[73]
- Butyl Benzyl Phthalate, (CASRN 85-68-7),[74] and
- Dibutyl Phthalate (CASRN 84-74-2).[75]

In short, the ongoing and planned TSCA review of phthalates obviates the need for a RCRA rulemaking now. A RCRA review would be a duplicative and less comprehensive effort

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[70] The Agency has begun to implement a "chemical as a whole" approach to making a safety determination that will trigger risk management rulemaking.

[71] EPA, *Final Scope of the Risk Evaluation for Di-ethylhexyl Phthalate (1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester) (Aug. 2020)*, https://www.epa.gov/sites/default/files/2020-09/documents/casrn_117-81-7_di-ethylhexyl_phthalate_final_scope.pdf.

[72] EPA, *Final Scope of the Risk Evaluation for Dicyclohexyl Phthalate (1,2- Benzenedicarboxylic acid, 1,2-dicyclohexyl ester) (Aug. 2020)*, https://www.epa.gov/sites/default/files/2020-09/documents/casrn_84-61-7_dicyclohexyl_phthalate_final_scope.pdf.

[73] EPA, *Final Scope of the Risk Evaluation for Di-isobutyl Phthalate (1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester) (Aug. 2020)*, https://www.epa.gov/sites/default/files/2020-09/documents/casrn_84-69-5_di-isobutyl_phthalate_final_scope.pdf.

[74] EPA, *Final Scope of the Risk Evaluation for Butyl Benzyl Phthalate (1,2-Benzenedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester) (Aug. 2020)*, https://www.epa.gov/sites/default/files/2020-09/documents/casrn_85-68-7_butyl_benzyl_phthalate_finalscope.pdf.

[75] EPA, *Final Scope of the Risk Evaluation for Dibutyl Phthalate (1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester) (Aug. 2020)*, https://www.epa.gov/sites/default/files/2020-09/documents/casrn_84-74-2_dibutyl_phthalate_final_scope_0.pdf.

imposing unnecessary administrative burdens.[76] As EPA completes its ongoing review of each of the 20 High-Priority substances in the coming year, the Agency must commence its review of another chemical. In selecting additional substances for review, EPA must work through any remaining substances on the 2014 TSCA Work Plan lists. Thus, EPA will address the remaining three phthalate plasticizers on the Work Plan list. As such, there is no basis to grant the Petition, even if plasticizers were relevant to the RCRA listing of PVC.

We note that vinyl chloride is another substance on the 2014 TSCA Work Plan list that is targeted for prioritization, risk evaluation, and risk management.[77]

V. Marine Waste and Microplastics are Being Addressed by Other Statutes

Since the Petition was filed in 2014, the marine waste issues raised by CBD have been addressed by Congress and the EPA, which is working with other agencies on implementation and reduction of marine waste. Enacted in December 2020, the Save Our Seas 2.0 Act has three main components:

> Title I – Combating Marine Debris: Strengthen the United States' domestic marine debris response capability with a Marine Debris Foundation, a genius prize for innovation, and new research to tackle the issue.
>
> Title II – Enhanced Global Engagement to Combat Marine Debris: Enhancing global engagement to combat marine debris by formalizing U.S. policy on international cooperation, enhancing federal agency outreach to other countries, and exploring the potential for a new international agreement on the challenge.
>
> Title III – Improving Domestic Infrastructure to Prevent Marine Debris: Improving domestic infrastructure to prevent marine debris through new grants for and studies of waste management and mitigation, including minimization of new plastic waste.[78]

The Save Our Seas 2.0 Act is integral to the Biden Administration's efforts. In December 2021, President Biden signed Executive Order 14057, "Catalyzing Clean Energy Industries and Jobs

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[76] Indeed, EPA's hazardous waste listing determination policy states that "if other Federal or State programs clearly regulate risk associated with the wastestream, listing may not be necessary to eliminate risk. . . . In some cases, another regulatory program may be in the process of developing such regulatory requirements. If this program is under statutory requirements or Court Order, EPA may consider these regulatory requirements to be forthcoming and, in some cases, may defer to them in listing determination, even where such regulatory coverage is several years away. If this program is under no statutory or legal deadline, no deference typically will be given to projected future regulatory coverage from other programs." *Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Dye and Pigment Industries; Hazardous Waste Listing Determination Policy; and CERCLA Hazardous Substance Designation and Reportable* Quantities, 59 Fed. Reg. 66,072, 66,078 (Dec. 22, 1994).

[77] TSCA Work Plan at p. 25 (chemical #87).

[78] Pub. L. 116-224.

Through Federal Sustainability."[79] Section 207 of the Order, "Reducing Waste and Pollution" states:

> Each agency shall minimize waste, including the generation of wastes requiring treatment and disposal; advance pollution prevention; support markets for recycled products; and promote a transition to a circular economy, as defined in section 2 of the Save Our Seas 2.0 Act (Public Law 116–224), by annually diverting from landfills at least 50 percent of non-hazardous solid waste, including food and compostable material, and construction and demolition waste and debris by fiscal year 2025; and 75 percent by fiscal year 2030.

On September 15, 2022, the Interagency Marine Debris Coordinating Committee, on which EPA and the National Oceanic and Atmospheric Administration participate, released a draft report on microfiber pollution required by the Save Our Seas 2.0 Act.[80]

We note this only to demonstrate that the antecedents of marine waste and microplastics are being addressed through a broad Executive Branch effort. This warrants careful consideration of the major question doctrine.[81] Moreover, as we demonstrate above and in **Attachment I**, PVC is not a significant component of marine and microplastic waste and many articles on these topics cited by Petitioners do not mention or include PVC. It would be unreasonable, arbitrary, and unwise for EPA to address marine and microplastic waste through listing of a single product under RCRA.

VI. Granting the Petition Would Undermine Other Policy Considerations Without Corresponding Benefit

The Petition requests that discarded PVC products be listed as a hazardous waste, even if the discarded products are not deemed hazardous under RCRA regulations and even if the products do not contain the hazardous constituents of concern to Petitioners. Thus, mere presence or possible presence of a substance is the criteria implied by the Petition, rather than the presence of risk.

From that perspective, virtually any product could be deemed a RCRA hazardous waste on discard. For example, formaldehyde is a natural component of wood.[82] Thus, all wood products

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[79] 86 Fed. Reg. 70,935 (Dec. 13, 2021).

[80] National Oceanic Atmospheric Administration, *Report on Microfiber Pollution - 2022 Report to Congress: Draft for Public Comment*, https://marinedebris.noaa.gov/sites/default/files/publications-files/Section_132_Draft_Report_on_Microfiber_Pollution_for_FRN_8Aug2022.pdf. A review of the draft report indicates that PVC products are not likely to be a major source of microfiber pollution.

[81] *West Virginia v. EPA*, 597 U.S. ___ (2022) (S. Ct. No. 20-1530).

[82] B. Meyer & C. Boehme, *Formaldehyde Emission from Solid Wood*, 47 Forest Products Journal at 45-48 (1997). "Abstract: Formaldehyde parameters of five European wood species were determined using test methods applicable for wood-based materials. The five wood species studied showed differences in their formaldehyde emissions. Samples of green oak produced values of 9 parts per billion of formaldehyde (the highest value) and dry beech wood produced 2 parts per billion of formaldehyde (the lowest value). The emission values determined in the dry state were 1 to 2 units higher than those in the green state, with the exception of oak."

are hazardous under the Petition's approach. A similar case could be made for metals, earth, and trace components of plants. Of course, wood and plants are not hazardous. The point is simply the absurd result of the Petition's premise.

PVC products are widely used in construction with applications ranging from water pipes, to siding, windows and doors, fence and decks, wire and cable, electrical conduit, wall coverings, and roofing. If the agency listed discarded PVC products as hazardous waste, nearly every construction site would need to alter its operations to ensure that discarded PVC products are identified and handled as hazardous waste. While PVC construction products have a long life and are deemed durable goods, all remodeling or demolition work practices would need to be adjusted with separation and management appropriate for hazardous waste.

Remodeling and demolition operations would become generators of hazardous waste, subjecting them to regulations governing on-site accumulation limits and technical standards, personnel training, contingency plan and emergency planning, preparedness and prevention, manifest, record keeping and reporting.[83] The compliance costs could cripple small businesses due to the collective costs of obtaining a permit for generator status, permit fees, required hazardous waste training, consultant fees, zoning and site restrictions for hazardous waste generators, increased insurance premiums, and a limited selection of banking or financial services to support operations involving hazardous waste generation.

This same scenario will be repeated for most health care settings, from hospitals to doctors' offices. Similar consequences apply to municipal and private drinking water systems given the wide use of PVC for water pipes. And our nation's farms and irrigation systems would be similarly affected. In the U.S., credit cards, driver's licenses, public transit passes, and other types of I.D. cards are, for the most part, made from PVC. These items, now carried in our purses and wallets, will become hazardous waste at the end of their useful life if discarded by retailers, financial institutions, and other businesses. The Petitioner's request would create massive disruption and costs without corresponding benefits by overturning the constituents policy.

Granting the petition also would have an adverse effect on the PVC industry's initiatives to advance post-consumer recycling. The industry has set a goal to increase post-consumer recycling from 146 million lbs/year to 160 million lbs per year by 2025. This goal is supported by a strategy of building coalitions within vinyl product markets supported by the vinyl value chain. Pilot demonstration programs are currently underway in roofing and siding and a new initiative is being developed for PVC used in healthcare. PVC that is recycled after consumer use should be considered raw material input to the product manufacturing process and not as waste. However, a large percentage of the potential material to be collected is currently being routed through construction and demolition waste sites. If the material is classified as hazardous at

[83] *See* 40 C.F.R. Part 262—Standards Applicable to Generators of Hazardous Waste. Summary table can be found at https://www.epa.gov/hwgenerators/hazardous-waste-generator-regulatory-summary.

disposal it will face regulatory obstacles to recycling under RCRA and stop the progress in material recycling.

The Petition also is inconsistent with Executive Order (E.O.) 12866, which established criteria for "a regulatory system that works."[84] As E.O. 12866's introductory paragraph notes:

> *The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. . . . .*
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> *Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.*[85]

Even without a formal regulatory impact analysis, it is evident that the requested hazardous waste listing would be a significant regulatory action that would exceed the $100 million annual effect on the economy and trigger multiple aspects of E.O. 12866. Besides the economic and productivity disruptions, the proposed action also would conflict with other EPA Office of Resource Conservation and Recovery programs such as the Office's circular economy efforts.[86]

A. Recycling

Resource efficiency and recycling is one of the impact categories the U.S. vinyl industry is addressing in its industry-wide sustainability initiative know as +Vantage Vinyl.[87] The Vinyl Institute became a signatory of the America Recycles Pledge in 2019 in support of EPA's mission to improve recycling in the U.S. In addition, more than 1 billion pounds of PVC/vinyl is recycled annually in the U.S. and Canada. Most of the recycled vinyl comes from industrial or

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[84] *Regulatory Planning and Review (September 30, 1993)*, 58 Fed. Reg. 51,735 (Oct. 4, 1993). See also, Executive Order 13610, Identifying and Reducing Regulatory Burdens, 77 Fed. Reg. 28,469 (May 14, 2012); and E.O. 13990, Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis, 86 Fed. Reg. 7037 (Jan. 25,2021).

[85] *Id.* at Section 1(a).

[86] EPA Website, *EPA's Office of Resource Conservation and Recovery (ORCR)*, [HYPERLINK "https://www.epa.gov/rcra/epas-office-resource-conservation-and-recovery-orcr"] (last visited Nov. 21, 2022).

[87] *See* [HYPERLINK "https://vantagevinyl.com/progress-report/"] for the 2020 Vinyl Sustainability Report and the 2015-2019 Our Sustainability Journey report. The report for 2021, which uses data from calendar year 2021, is being drafted, but additional information can be reviewed at [HYPERLINK "https://vantagevinyl.com/?s=recycling"].

pre-consumer recycling but post-consumer recycling of vinyl products has increased significantly. Since 2014, there has been a 40-percent increase in post-consumer recycling. More and more vinyl products are finding their way into the recycling stream. Approximately 146 million pounds of consumer vinyl products are recycled annually.

The U.S. vinyl industry is focused on diverting vinyl products from the landfill. According to EPA statistics, around 1.9 billion pounds of vinyl products are landfilled today in the U.S. The vinyl industry is working to divert more products from the landfill and into recycling streams.[88] There are over 100 vinyl recyclers in the U.S. and Canada. The VI hosts a recycling directory that identifies recyclers by state and province.[89] The result of the Petitioner's proposal would be reduced recycling and reduced resource conservation.

B. Low Embodied Carbon

PVC is a low embodied carbon material that also is critical to tackling climate change, a global priority that is shared by EPA and this Administration. Executive Order 14008, *Tackling the Climate Crisis at Home and Abroad*, states that it is the policy of the Administration to deploy the full capacity of federal agencies to combat the climate crisis to implement a government-wide approach that increases resilience to the impacts of climate change.[90] E.O. 14008 also directed agencies to develop action plans with steps each agency can take to bolster adaptation and increase resilience to the impacts of climate change. In October 2021, EPA released its 2021 Climate Adaptation Action Plan.[91] The plan states that EPA will ensure its programs, policies, rules, enforcement, and compliance assurance activities consider current and future impacts of climate change. Because of its low embodied carbon profile, PVC helps buildings and other applications address climate change issues.

A McKinsey & Company study report concludes that PVC pipes play an important role in reducing greenhouse gas emissions (GHGs). In both gravity sewer and force main applications, PVC has lower GHG emissions — 45% lower than reinforced concrete and 35% lower than ductile iron. Concrete and ductile pipes also require more GHG-intensive transport and installation processes. Pumping efficiency for force main pipes also favors PVC.[92]

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[88] Vinyl Institute Website, *Recycling*, [HYPERLINK "https://www.vinylinfo.org/recycling/"] (last visited Nov. 21, 2022).

[89] Vinyl Institute Website, *Recycling Directory*, [HYPERLINK "https://www.vinylinfo.org/recycling-directory/"] (last visited Nov. 21, 2022).

[90] 86 Fed. Reg. 7619, 7622 (Feb. 1, 2021).

[91] EPA, *Climate Adaptation Action Plan (Oct. 2021)*, [HYPERLINK "https://www.epa.gov/system/files/documents/2021-09/epa-climate-adaptation-plan-pdf-version.pdf"].

[92] McKinsey & Company, *Climate Impact of Plastics*, p. 10 and 18 (July 2022). Available at [HYPERLINK "https://www.mckinsey.com/~/media/mckinsey/industries/chemicals/our%20insights/climate%20impact%20of%20plastics/climate-impact-of-plastics-v2.pdf"].

The Inflation Reduction Act of 2022 was enacted on August 16.[93] Energy efficiency, climate change, and environmental justice permeate the statute as represented by encouraging building energy efficiency, electric automobiles, emissions reduction accompanied by state and local grant and bond programs. This is not a regulatory statute. Rather, the research, grants, and other funding are intended to serve as a catalyst for addressing climate change, increased energy efficiency, and more equitable distribution of services and protections. The Act promotes the use of low-embodied carbon construction materials, such a PVC, and directs EPA to develop the program.[94]

The Infrastructure Investment and Jobs Act[95] and its implementing Executive Order[96] include not only transit but also funding for clean water and electric grid renewal, applications for which PVC serves a critical role. Because of the adverse effects on construction and infrastructure, the proposed action runs counter to recent legislation to rebuild infrastructure.

The US Green Build Council (USGBC) completed a four-year study in 2007 to evaluate the technical and scientific basis for a PVC-related materials credit as part of the LEED Green Building Rating System.[97] The evidence collected during the study led the Technical Science Advisory Committee (TSAC) to conclude that a credit rewarding avoidance of PVC could steer decision makers toward using materials that are *worse* for human and environmental health. The evidence also served as a basis for "increased use of integrated methods for material evaluation, not only to pass judgement on a particular credit for a particular material." In addition, the recommendation encouraged the development of credits informed by life cycle assessments (LCA) and risk assessments that use a systematic, comprehensive, whole-building approach to critical issues such as bioaccumulative pollutants, particulate emissions, and climate change.

Listing PVC products will lead to the use of products with a worse environmental profile, less tested performance properties, and be counterproductive to carbon reduction goals.

C. Regulatory Policy and Fairness

Given these vast consequences, sound regulatory policy and fundamental fairness requires the review of additional considerations. As a matter of reasonable regulation, EPA must first determine what new and improved regulatory regime would replace its current constituents policy and what data and science support any new scheme. Fundamental fairness requires that EPA design its approach for all materials and not PVC in isolation. This is not the usual case of

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[93] Pub. L. No. 117-169.

[94] Inflation Reduction Act § 60116 promotes this through labeling of a products embodied carbon properties.

[95] Infrastructure Investment and Jobs Act, Pub. L. 117–58, 135 Stat. 429 (2021).

[96] E.O. 14052 Implementation of the Infrastructure Investment and Jobs Act, 86 Fed. Reg. 64,335 (Nov. 18, 2021).

[97] U.S. Green Building Council, Board of Directors, *Memorandum -TSAC Report on PVC* (Feb. 26, 2007), [HYPERLINK "https://s3.amazonaws.com/legacy.usgbc.org/usgbc/docs/Archive/General/Docs2372.pdf"].

applying existing regulations and policy to a substance. Rather, it is reminiscent of major question doctrine analyses.[98]

Should the Agency entertain the petition, it will be obligated to provide detailed analyses under the:

- Congressional Review Act[99]
- Regulatory Flexibility Act[100] (RFA) and its
- Small Business Regulatory Enforcement Fairness Act provisions[101]
- Unfunded Mandates Reform Act[102] Given the impact on state and local budgets for waste management, construction and infrastructure, the analysis should include a cost-benefit assessment with a description of the macro-economic effects and a cost-benefit analysis.

Given inherent problems with the Petition's regulatory approach, conflicts with legislative and Administration initiatives, and on-going reviews under TSCA, EPA must reject the Petition.

VII. Conclusion

In summary, CBD's Petition is based on inaccurate information and does not include all the literature on PVC or its constituents. CBD's petition also fails to account for and would overturn the existing regulatory approach for discarded PVC products and all other products with any hazardous constituent. Further, PVC products are widely varied and thus not appropriate for assessment as a single material. Finally, the 2016 amendments to TSCA and the Agency's existing chemical review process weigh against separate action under RCRA. As a result, CBD's arguments for regulation under RCRA fail to meet the standards for rulemaking under these statutes. The 2014 CBD petition should be denied.

If you have any questions or require additional information regarding this submission, please do not hesitate to contact me.

Respectfully submitted,

Ned Monroe
President and CEO

Attachment

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[98] *West Virginia v. EPA*, 597 U.S. ___ (2022) (S. Ct. No. 20-1530).

[99] 5 USC § 801 et seq. (1996).

[100] 5 USC § 601.

[101] Pub. L. No. 104-121.

[102] 2 USC § 1501 et seq. (1995).

Attachment 1, *Vinyl Institute Comments on Center for Biological Diversity Petition References*

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